

HISTOACRYL® and HISTOACRYL® BLUE TOPICAL SKIN ADHESIVE

Package Insert



Before using product, read the following information thoroughly.

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

IMPORTANT! This insert is designed to assist in using the Histoacryl® tissue adhesive. It is not a reference to surgical techniques.

DESCRIPTION

Histoacryl® and Histoacryl® Blue are sterile liquid topical skin adhesives composed of n-Butyl-2-Cyanoacrylate monomer. The two products are different in only one respect: Histoacryl® is provided as a colorless liquid, and Histoacryl® Blue is colored with the dye D&C Violet #2 in order to make it easier to see the thickness of the layer of Histoacryl Blue that has been applied. Histoacryl® and Histoacryl® Blue topical skin adhesives are supplied in a 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within a plastic vial so the exterior of the ampoule can remain sterile. Histoacryl® remains liquid until exposed to acid, base, alcohol, water or water-containing substances, including tissues; upon contact with water or water-containing substances such as tissues. Histoacryl cures (polymerizes exothermically) and forms a film that bonds to the underlying surface. All references to Histoacryl® below refer to both Histoacryl® (without dye) and Histoacryl® Blue (with dye) unless stated otherwise.

INDICATIONS

Histoacryl and Histoacryl Blue topical skin adhesives are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl and Histoacryl Blue may be used in conjunction with, but not in place of, dermal sutures.

CONTRAINDICATIONS:

- Histoacryl® topical skin adhesive is not to be applied to below the surface of the skin, epidermis. The liquid adhesive will react exothermically with tissue; the polymerized adhesive is not absorbed by any tissues and may elicit a foreign body reaction.
- The topical skin adhesive is not to be applied to any internal organs, blood vessels, nerve tissue, mucosal surfaces or mucocutaneous junctions, areas with dense natural hair, or within the conjunctival sac of the eye.
- The topical skin adhesive is not to be applied to the surface of the eye. If the eyelids are accidentally bonded closed, release eyelashes with warm water by covering with a wet pad. The adhesive will bond to eye protein and will cause periods of weeping which will help to debond the adhesive. Keep the eye covered until debonding is complete – usually within 1 to 3 days. Do not force the eye open.
- The topical skin adhesive is not to be applied to wounds subject to high skin tension, or on areas of increased skin tension such as the elbows, knees, or knuckles. The topical skin adhesive is not to be used in areas of skin excision.
- The topical skin adhesive is not to be applied to wounds that show evidence of infection, gangrene or wounds of decubitus etiology.
- The topical skin adhesive is not to be used on patients with known preoperative systemic infections, uncontrolled diabetes, or diseases or conditions that are known to interfere with the wound healing process.
- The topical skin adhesive is not to be used on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, or the dye D&C Violet #2.

WARNINGS:

- Histoacryl® topical skin adhesive should be used only on wounds that have been thoroughly cleaned, debrided and have easily apposed wound edges.
- The topical skin adhesive generates a small amount of heat during polymerization and should not be applied to tissues that may be affected by such heat.

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- The adhesive should always be applied very sparingly, either as minute drops or as a very thin film along the edges of the wound. Heavy application may cause thermal damage to tissues, and delayed healing may result.
- The topical skin adhesive should not be applied to wet wounds. Excess moisture, such as water or alcohol, may accelerate polymerization, resulting in the generation of excess heat.
- Use of the topical skin adhesive may result in localized sensitization or irritation reactions.
- Application and/or migration (leak) of either version of the product below the surface of the epidermis will impair the healing process by forming a barrier between tissue edges.
- Histoacryl Blue migration (leak) below the epidermal surface may result in "tattooing" of the underlying tissue.
- Histoacryl Topical Skin Adhesive will readily adhere to most substrates. Care should be taken to avoid unwanted contact with the adhesive during polymerization. Polymerized adhesive can be removed from metal instruments with acetone. Accidental bonding of materials other than tissues may be reversed by peeling apart the adhered surfaces with the aid of warm soapy water, petroleum gel, saline solution, or 5% solution of sodium bicarbonate.
- Accidental bonding of unwanted skin may occur. Do not pull apart skin. Instead, accidental bonding of unintended areas of skin of the body can be corrected with the use of acetone or by soaking in warm water until the skin may be separated.

PRECAUTIONS:

- Wounds should be kept dry following closure with the topical skin adhesive. Do not apply topical medications following closure.
- In the event of spillage, Histoacryl® topical skin adhesive can be absorbed with talc. Flush area with water to solidify the adhesive.
- Histoacryl® topical skin adhesive has not been evaluated in patients with a history of hypertrophic scarring or keloid information.
- Small quantities of Histoacryl® should be used during wound repair, because use of excess Histoacryl® can result in tissue damage due to the cumulative heat dissipated during device polymerization.

ADVERSE REACTIONS

In studies¹⁻⁴ with 1338 patients and 1492 wounds, the following adverse reactions were reported:

Table 1 Adverse Reactions¹⁻⁴

Adverse Reactions	Amiel et al ¹	Barnett et al ²		Quinn et al ³		Bruns et al ⁴	
	Histoacryl®	Histoacryl®	Sutures	Histoacryl®	Sutures	Histoacryl®	Sutures
N, patients treated	1033	83	80	41	40	30	31
N, wounds treated	1150	100	100	41	40	30	31
Dehiscence**							
Dehiscence-at Any Time	11 (1.1%)	0/62	0/40	3(8.1%)	2 (5.3%)	1 (3.0%)	1 (3.0%)
Wound Edge Separation Requiring Re-Treatment	1	0	0	2	1	0	0
Infection***							
Suspected Infection	ND	0/62	2/49	1/37 (2.7%)	1/38 (2.6%)	1/30 (3.0%)	ND
Acute Inflammation							
Erythema	57 (5.5%)	ND	ND	1 (2.7%)	4 (11.5%)	ND	ND
Edema	5 (0.5%)	ND	ND	ND	ND	ND	ND
Drainage	20 (1.9%)	ND	ND	ND	ND	ND	ND

ND - No data reported

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** Dehiscence was defined as: 1) separation of the incision that required medical attention and that almost exclusively was closed by secondary intention (i.e., Amiel et al¹) or 2) a wound coming apart by the 7 days follow up visit (i.e., Barnett et al²) or a wound requiring delayed primary closure (Quinn et al³). A prospective definition for dehiscence was not provided in Bruns et al⁴.

*** Infection was defined as: 1) a wound requiring antibiotic treatment (i.e., Amiel et al¹ and Bruns et al⁴) or 2) an area of redness around the wound with or without discharge (i.e., Barnett et al²). A prospective definition for wound infection was not provided in Quinn et al³.

POTENTIAL ADVERSE EFFECTS

Clinical experience with Histoacryl used outside the United States suggests that the following adverse events, (not reported in the above cited studies), may occur: bonding to unintended tissues, thermal discomfort during polymerization, allergic reaction, foreign body reaction, tattooing, and chronic non-healing of a wound.

CLINICAL STUDIES

The results of four clinical studies performed with Histoacryl® are summarized below.

1. Amiel et al¹

A. Study Design

The study was an open-label retrospective trial designed to evaluate the safety and effectiveness of Histoacryl Blue in approximating surgical incisions at three Israeli centers.

The study population included pediatric patients undergoing elective surgical incisions (i.e., orchidopexy, inguinal hernia, umbilical hernia or hydrocele repair). All incisions were 2 and 5 cm in length, closure was achieved with standard surgical techniques by attending physicians, and final cutaneous closure was performed with Histoacryl.

Patients were discharged after 4-6 hours of observation. Follow-up visits were 7 days and 4 to 8 weeks (if needed) after surgery. A 12-item questionnaire was completed during a telephone interview with a family member within 6 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics is presented in Table 2.

Table 2: Patient Accounting, Demographics, Wound Characteristics Summary reported by Amiel et. al¹

Accounting		No. of pts (%)
Patient records reviewed		1098
Patients treated with Histoacryl		1033 (100%)
Wounds treated with Histoacryl		1150
Patients completing 7 day follow-up		905 (87.6%)
Patients attending 4 week follow-up		401 (38.8%)
Surgical Procedure		N (%)
Right inguinal hernia repair		407 (37%)
Left inguinal hernia repair		199 (18%)
Bilateral inguinal hernia repair		119 (11%)
Umbilical hernia repair		43 (4%)
Hydrocele repair		167 (15%)
Orchidopexy		163 (15%)
Patient Age		1 mo – 16 yrs
Wound Characteristics		
Length (cm)	range	2 – 5
Depth		ND
Width		ND
Class		ND
Incisions		1150
Lacerations		0
Local Anesthetic use		
Patients using local anesthetic		1033 (100%)

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ND - No data reported

C. Study Outcomes

The adverse reactions observed in patients are described in Table 1. 1022/1033 (98.9%) of the patients treated with Histoacryl achieved wound closure without dehiscence (i.e., separation of the incision that required medical attention).

2. Barnett et al.²

A. Study Design

The study was a prospective, randomized trial designed to compare the safety and effectiveness of Histoacryl Blue and sutures in closing simple pediatric lacerations in an emergency room setting at three facilities in Australia and New Zealand.

Patients between the ages of 4 -12 years were enrolled if they had a clean laceration on any part of the body that was less than 5 cm in length. Patients were excluded if the wound occurred on the eyelid, mucous membrane or a joint margin (i.e. under any added tension) or if the wound required debridement or plastic surgery.

Patients were assessed after wound closure and at 1 week, 3 and 12 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics is presented in Table 3.

Table 3: Patient Accounting, Baseline Demographics
and Wound Characteristics Reported in Barnett et al²

		Histoacryl Blue	Control Sutures
Patient Accounting			
N, patients enrolled		83	80
N, patients treated		83	80
Patients completed:	1 week	62 (74.6%)	49 (61.2%)
	90 days	46 (55.0%)	44 (55.0%)
	12 months	36 (43.0%)	34 (43.0%)
Patient Demographics			
Mean Age in months (standard deviation)		69.5 (29)	68.4 (30)
Males		48 (57.8%)	68 (85%)
Wound Characteristics			
Length in cm	mean	1.54	1.68
Depth in cm	mean	ND	ND
Width in cm	mean	0.34	0.28
Wound Class: Clean		100 (100%)	100 (100%)
Incisions		0	0
Lacerations		100 (100%)	100 (100%)
Face		49	64
Scalp		35	29
Other		16	7
Use of Anesthesia			
General		0	0
Local only		0	80 (100%)
None		83 (100%)	0

ND – No data reported

C. Study Outcomes

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The adverse reactions observed in patients are described in Table 1. Closure of all 200 (100%) wounds was achieved in both treatment groups without dehiscence (i.e., a wound that came apart by the 7 day follow up visit).

3. Quinn et al³

A. Study Design

This study was a prospective, randomized controlled trial comparing closure of pediatric facial lacerations with Histoacryl Blue and sutures in a single Canadian Emergency room facility.

Patients, under the age of 18, with clean facial lacerations less than 4 cm in length and 0.5 cm in width were eligible for enrollment. Patients with wounds requiring deep layer closure, caused by animal bites, lacerations on hair-bearing surface, crossing mucocutaneous junctions or heavily soiled and requiring debridement were excluded from enrollment.

Patients were evaluated immediately after treatment as well as 5 days and 3 months after wound approximation.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics are presented in Table 4.

Table 4: Summary of Patient Accounting, Baseline Demographics
and Wound Characteristics Reported by Quinn³ et al.

	Histoacryl Blue	Control Sutures
Patient Accounting		
N, patients enrolled	41	40
N, patients treated	37	38
Patients completed: 90 days	33 (89.1%)	36 (94.7%)
Patient Demographics		
Age (years)	0.7-16	0.5-15
Mean (years)	4.7	4.5
Sex (Male)	58%	42%
Wound Characteristics		
Length in cm mean	1.53	1.52
Depth	ND	ND
Width	ND	ND
Wound Class:	ND	ND
Incisions	0	0
Lacerations (Facial)	37 (100%)	38 (100%)
Use of Anaesthesia		
General	0	0
Local only	0	38 (100%)
None	37(100%)	0

ND – No data reported

C. Study Outcomes

The adverse reactions observed in patients are described in Table 1. Wound closure without dehiscence (i.e., wounds requiring delayed primary closure) was achieved in 34/37 (91.9%) of the Histoacryl and 36/38 (94.7%) of the suture-treated patients.

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4. Bruns et al⁴

A. Study Design

This study was a prospective, randomized trial comparing closure of pediatric lacerations with Histoacryl Blue and sutures at three emergency rooms within the U.S. All lacerations received routine wound management and lacerations greater than 5 mm in depth were initially repaired with subcutaneous sutures. Patients were then randomized to final cutaneous closure by either Histoacryl or suture.

Patients between the ages of 1 – 18 years old with lacerations less than 5 cm were enrolled. Wounds requiring the use of subcutaneous sutures were enrolled in this study. Patients with lacerations in areas of high skin mobility or tension (e.g., joints, hands, feet, eyelids, ears, nose, mouth or perineum) were excluded from the study as were lacerations caused by dog bites or extending to the muscle or bone.

Patients were evaluated after wound closure and at 1 week and 2 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics is presented in Table 5.

Table 5: Summary of Patient Accounting, Baseline Demographics
and Wound Characteristics Reported by Bruns et al⁴

Patient Accounting		Histoacryl	Sutures
N, patients treated		30	31
N, wounds treated		30	31
Attending 2 month visit		30	25
Baseline Demographics			
Median Age		4 years	3 years
Gender (G: male)		24 (80)	25 (80)
Race			
White		14 (47)	19 (61)
Black		16 (53)	12 (39)
Wound Characteristics			
Length in cm	median	1.5	1.5
Depth			
< 5 mm		22 (73%)	22 (71%)
> 5 mm		8 (27%)	9 (29%)
Width		ND	ND
Wound Class:		ND	ND
Incisions		0	0
Lacerations (Facial)		37 (100%)	38 (100%)
Local Anesthetic used			
Patients treated with anesthetic		13/30 (43%)	31/31 (100%)

ND – No data reported

C. Study Outcomes

The adverse reactions observed in patients after surgery are described in Table 1. Wound closure without dehiscence (i.e., no prospective definition was provided) was achieved in 29/30 (96.7%) of the Histoacryl and 30/31 (96.8%) of the suture-treated patients.

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HOW SUPPLIED

Histoacryl® topical skin adhesives are supplied in 0.5ml single patient use, ampoules. The ampoule has been sealed in a plastic tube (sealed pouch). Histoacryl® Blue topical skin adhesive is supplied in boxes containing 10 unit doses. Histoacryl® is also available without the dye in 0.5ml single patient use, in boxes of 5 unit doses.

INSTRUCTIONS FOR USE

1. Inspect and clean the wound, provide local anesthesia for adequate cleansing and debridement of any devitalized structures, assure hemostasis, close the dermis as needed, and assure that surface edges are easily appposable before applying topical skin adhesive.
2. For wounds that may be at risk for tension, before applying Histoacryl topical skin adhesive to the skin surface, provide relief of potential stress along the wound line by approximating wound edges with subcuticular sutures.
3. Remove the cap of the plastic vial to expose the sterile, single patient use ampoule.
4. Before opening the ampoule, hold it in one hand with the tip pointed upward. Sharply flick the tip with the forefinger of the other hand to remove any adhesive trapped in the tip during transit. While still holding the ampoule in the vertical position, snip or cut the closed tip end of the ampoule to open.
5. To express Histoacryl®/Histoacryl® Blue from the ampoule tip, apply light pressure to the ampoule.
6. Appose tissue edges with forceps and hold in apposition while applying Histoacryl and for approximately 30 seconds after application to allow Histoacryl to cure and to prevent seepage between wound edges.
7. Apply Histoacryl® Blue topical skin adhesive to the easily apposed wound edges very sparingly, either as minute drops or as a very thin film along the top edges of the wound. Avoid heavy application.
8. After applying Histoacryl, maintain light pressure along the wound line to maintain apposition for approximately 30 seconds to allow the topical skin adhesive to cure.
9. After Histoacryl application and cure, discard the ampoule with any remaining adhesive by putting the ampoule in the original plastic cylinder and putting the original stopper on the cylinder.

PATIENT INSTRUCTIONS (Available in a separate sheet for distribution to the patient)

The following information should be shared with the patient:

- Avoid contact with water for the first 24 hours after treatment and minimize contact with water for an additional 7-10 days. For example, do not shower, bathe or swim for 48 hours following wound closure and do not scrub or soak the wound in water for 7-10 days.
- Do not apply any medications or cream to the wound.
- Keep the wound dry with a non-stick, non-medicinal and water resistant bandage, per your doctor's instructions.
- Do not pull or pick at the wound or bandage.
- Avoid extreme physical activity that might dislodge or impact the wound surface.
- Report any discomfort, redness, drainage, swelling or other concerns regarding your wound to your doctor.

STORAGE

- Histoacryl® topical skin adhesive should always be stored in its original sealed plastic tube.
- During prolonged (i.e., greater than 24 hours) periods, Histoacryl®/Histoacryl® Blue topical skin adhesives should be kept refrigerated at temperature from 36°F (2°C) to 41°F (5°C).
- Avoid prolonged (i.e., greater than 8 hours) exposure to elevated (i.e., 104-140°F, 40-60 °C) temperatures.
- Histoacryl®/Histoacryl® Blue topical skin adhesive should not be used after the expiration date shown on the plastic tube, preceded by the expiration symbol.

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STERILITY:

Histoacryl topical skin adhesive is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged.

References

1. Amiel GE, Sukhotnik I, Kavar B, and Siplovich L, "Use of N-Butyl-2-cyanoacrylate in Elective Surgical Incisions- Longterm Outcomes," *J Am Coll Surg*, **Vol 189**, 21-25 (1999)
2. Barnett P, Jarman FC, Goodge J, Silk G, and Aickin R, "Randomized trial of Histoacryl Blue tissue adhesive glue versus suturing in the repair of pediatric lacerations," *J. Paediatr. Child Health* **34**, 548-550 (1998)
3. Quinn JV, Drezwiecki A, Li MM, Stiell IG, Sutcliffe, Elmsie TJ, and Wood WE, "A Randomized, Controlled Trial Comparing Tissue Adhesive With Suturing in the Repair of Pediatric Facial Lacerations," *Annals of Emergency Medicine*, **22 (7)**: 1130-1135 (1993)
4. Bruns TB, Simon HK, McLario DJ, Sullivan KM, Wood RJ, and Anand KJS, "Laceration Repair Using a Tissue Adhesive in a Children's Emergency Department," *Pediatrics*, **98**, 673-675 (1996)

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Histoacryl® Topical Skin Adhesive Patient Instructions Description of Histoacryl®

Your doctor has chosen to use Histoacryl® as a method for closing your wound. Histoacryl® is a sterile, liquid skin glue that holds wound edges together. The film will usually remain in place for 5 to 10 days, and then naturally fall off your skin. No additional or special care is needed for wounds closed using Histoacryl® other than following the instructions below. Histoacryl® is a quick setting glue made from cyanoacrylate which is a substance that bonds upon contact with a small amount of water as is found in human tissue.

Contraindications, Warnings and Precautions Relevant to Patient Care

- *Use of the topical skin adhesive may result in localized sensitization or irritation reactions.*
- *Wounds should be kept dry following closure with the topical skin adhesive. Do not apply topical medications following closure.*
- *Histoacryl® topical skin adhesive has not been evaluated in patients with a history of hypertrophic scarring or keloid information*

Risks and benefits

As with any wound, there is always a risk of infection. Studies have shown that the risk of infection using Histoacryl® is no different from the risk of using stitches, the alternate method of wound closure. Another risk is the splitting or opening of the wound (dehiscence). Studies have shown that the risk of dehiscence is no different from using stitches, the alternate method of wound closure. Information on the clinical studies conducted on Histoacryl® is presented at the end of this brochure. See *Additional Information*.

For Histoacryl to work correctly observe these important patient do's and don'ts

- *First 48 hours: Do keep your wound completely dry for at least 48 hours following wound closure. Do not swim, shower, or bathe.*
- *Next 5 to 8 days: Do not soak or scrub the wound in water. Try to avoid getting the wound wet during this time.*
- *Do not apply any medications or creams to the wound.*
- *Keep the wound dry and protected with a water resistant non-medicated bandage, per doctor's instructions.*
- *Change the bandage per doctor's instructions.*
- *Keep the adhesive part of the bandage off of the wound's edges.*
- *Watch the wound's appearance as healing progresses. A small amount of swelling, pain, or redness that goes away within a few days is common during wound healing. If these symptoms worsen or persist, please contact your doctor.*

Cautions

- *Never pick, pull, or scratch the wound or its bandage. This may cause the wound to re-open.*
- *Contact your doctor if the wound reopens or the edges separate.*
- *Contact your doctor if you have an infection, the signs are: increased discomfort, redness, swelling, discharge from the wound or if the wound feels warm to the touch.*
- *Do not expose the wound to long periods of sunlight or tanning lamps during the healing period*

Importance of the need to adhere to the care regimen

The instructions above are designed to optimize your healing and prevent infection. Also, the final appearance of the wound may depend on how well you followed the instructions and how well the wound heals.

How Histoacryl® is used

Your doctor makes this decision. Histoacryl® topical skin adhesive is intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations (cuts). Histoacryl® may be used along with but not in place of stitches.

Description of the procedure associated with the device

Before using Histoacryl® your doctor will decide if it is appropriate to use the tissue adhesive or whether stitches would be more appropriate. The wound will then be cleaned and dried prior to application of the adhesive. Your doctor will remove any foreign material in the wound (debride) when necessary. Your doctor may choose to use a local anesthetic. Your doctor will then open the container (vial) of adhesive and while squeezing the vial, apply small amounts of adhesive to the wound edges. Your doctor will push the wound edges together to close the wound. The adhesive will "set" and hold the wound edges together in typically less than a minute. Your doctor will cover the wound according to standard procedure. Your doctor will then give you any special instructions for you to follow.

Additional Information: Clinical Studies

Histoacryl® has been shown to be safe and effective in multiple clinical studies. Extensive chemical and mechanical testing has been performed as well. Four of the clinical studies are summarized here.

Amiel et al, 1999

This studied the Use of Histoacryl® in elective surgical incisions- long term outcomes. The results demonstrated that administration of Histoacryl® for the closure of small low-tension surgical incisions in the pediatric population is both safe and effective.

Barnett et al. 1998

This was a randomized trial of Histoacryl® tissue adhesive glue versus suturing in the repair of pediatric lacerations. The study demonstrated that the use of glue is both safe and effective.

Quinn et al, 1993

This was a randomized, controlled trial comparing a tissue adhesive with suturing in the repair of pediatric facial lacerations. This study concluded that Histoacryl® is a safe and effective method of closing wounds.

Bruns et al, 1996

This was a study of laceration repair using a tissue adhesive in a children's emergency department. It concluded that the use of (Histoacryl® Blue) for laceration repair is an acceptable alternative to conventional suturing.

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1. Amiel GE, Sukhotnik I, Kavar B, Siplovich L, Use of N-Butyl-2-cyanoacrylate in Elective Surgical Incisions- Longterm Outcomes. J Am Coll Surg Vol 189, No. 1, July 1999, 21-25
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4. Bruns Thomas B. Simon Harold K. McLario David J. Sullivan Kevin M. Wood Robert J. Anand K.J.S. Laceration Repair Using aTissue Adhesive in a Children's Emergency Department , Pediatrics 1996;98:673-675